APPENDIX A: 510(k) SUMMARY

JUN 16 2011

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Gurvinder Singh Nanda Manager, Regulatory Affairs Phone: (650) 687-5414 Fax: (650) 687-4449
Date of Submission:	March 2, 2011
Device Trade Name:	Tula™ Iontophoresis System
Common Name:	Iontophoresis System with Headset
Device Classification:	Class III
Regulation Number:	21 CFR 890.5525
Classification Name:	Device, Iontophoresis, Specific Uses
Product Code:	EGJ
Predicate Device:	Iontophoresis System (K073276) manufactured by Acclarent
Device Description:	The Iontophoresis System with Headset (IPSHS) is a single-use device that employs electric current to transport drug solution, salts, or ions in the ear, including the tympanic membrane. IPSHS consists of four components: a Control Unit, a Headset, Ear Plugs, and a Return Electrode Patch. The accessories to IPSHS include a Syringe, a Fill Nozzle, and a set of Ear Plug Sizers.
Indications for Use:	The Iontophoresis System with Headset is indicated for the administration of drug solution, salts, or ions into the ear, including the tympanic membrane, for medical purposes.
Technological Characteristics	IPSHS delivers an electrical current to the ear. The electrical current transports drug solution, salts, or ions in the ear, including the tympanic membrane.
Performance Data	IPSHS met all performance testing acceptance criteria.

Summary of Substantial Equivalence:	IPSHS is substantially equivalent to the predicate Device as confirmed through relevant performance tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Gurvinder Singh Nanda
Accalarent, Inc.
1525-B O'Brien Drive
Menlo Park, CA 94025

JUN 16 2011

Re: K110636
Trade/Device Name: Tula Iontophoresis System
Regulation Number: 890.5525(b)
Regulation Name: Iontophoresis Device
Regulatory Class: III
Product Code: EGJ
Dated: June 3, 2011
Received: June 6, 2011

Dear Dr. Nanda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the device as described below. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation

(21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, there are concerns relating to the fact that no drug is currently labeled for administration via an iontophoresis device. The Agency currently is evaluating this public health concern regarding the safety and effectiveness of this route of administration of drugs, and in the near future will inform manufacturers of certain additional steps the Agency believes are necessary to address this concern.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K11XXXX**

Trade Name: Tula™ Iontophoresis System

Common Name: Iontophoresis System with Headset

Indications For Use: The Iontophoresis System with Headset is indicated for the administration of drug solution, salts, or ions into the ear, including the tympanic membrane, for medical purposes.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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(Posted November 13, 2003)

510(k) Number K110636